REMARKS

By the *Office Action* of 19 May 2005, Claims 2-20 and 24-26 are pending in the Application, and all rejected. By the present *Response and Amendment with RCE*, the Applicant amends Claims 24 and 25, cancels Claim 20, provides a new Claim 27, and presents several distinguishing features between the clarified Claims and the cited references, and in so doing, believes the rejection of the Claims in view of the cited art is overcome. As amended, Claims 2-19 and 24-27 are now pending.

1. Call with Examiner, and *Petition for Revival*

On 22 November 2005, the Examiner contacted Applicant's representative requesting whether a *Response* had been filed to the 19 May 2005 *Office Action*. Applicant's representative indicated that as of 22 November 2005, no *Response* was filed in reply to that outstanding *Office Action*.

As of that date, Applicant's representative had not received instructions from Applicant to respond to the pending *Office Action*. Unbeknownst to the Applicant's representative, all rights to the invention and the pending patent application had been assigned to VHA Inc., who subsequently contacted the Applicant's representative indicating that a response to the *Office Action* should be filed. Accordingly, a *Petition for Revival of an Application for Patent Abandoned Unintentionally Under 37 C.F.R. § 1.137(b)* is filed herewith.

2. Notification of Loss of Small Entity Status

As the rights to the invention and the patent application have been assigned to VHA, Inc., a corporation which does not qualify for small entity status, this new Applicant respectfully submits a notice of loss of small entity status under 37 C.F.R. § 1.27(g)(2). The undersigned attorney for Applicant herein makes written assertion as to the appropriateness of the loss of small entity status.

3. No New Matter is Believed Introduced

In the 19 May 2005 *Office Action*, the previous *Response and Amendment* dated 17 February 2005 is objected to under 35 U.S.C. § 132 for the introduction of new matter into the disclosure. More specifically, Examiner asserts that newly added Claim 25 introduces limitations that were not supported in the originally-filed *Specification* and claims.

Further, newly added Claims 25-26 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the *Specification* in such a way as to

reasonably convey to one skilled in the art that the inventor(s), at the time of the application was filed, had possession of the claimed invention. Examiner asserts that independent Claim 25 recites new matter and is therefore rejected, while Claim 26 depends on Claim 25, and is thus rejected for the same reasons.

Applicant respectfully traverses the objection to the *Specification* and the rejection of the claims, because the *Specification*, as originally-filed on 13 December 2000, adequately supports the newly added limitations of Claim 25 and 26. Applicant, however, herein further clarifies Claims 24 and 25, and introduces new Claim 27. To address the Examiner's concern for new matter, Applicant provides the following support (within the *Specification*) for currently pending Claims 24-27 as they are pending upon entrance of this *Response and Amendment with RCE.*

a. Claims 24-27 Are Supported By The Originally-Filed Application

i. Claim 24

As clarified herein, Claim 24 provides for a computer-implemented method of increasing resource utilization efficiency and identifying areas to enhance quality, the method comprising the elements of (a) collecting data related to a specific clinical procedure, wherein the collected data is electronically stored in a database; (b) identifying from the collected data reduction opportunities for reducing waste and costs during the specific clinical procedure; (c) establishing a benchmark related to the specific clinical procedure based upon the identified reduction opportunities and at least a portion of the data; and (d) standardizing the specific clinical procedure based upon the benchmark.

Element (a) is herein clarified to include the limitation of "wherein the collected data is electronically stored in a database". Support for storing collected data in a database can be found in the *Specification* on at least page 6, lines 6-16; page 8, lines 1-2 of the last paragraph (e.g., "...reports are generated from the data entered and stored in the database"); and page 10, line 30 through page 11, line 1 (e.g., "...the data from allocating the resources and conducting the procedure is collected and stored in the database"). Also, element (a) was amended in the previous *Response and Amendment* to include the term "specific" and was not objected to by the Examiner for introducing new subject matter. As addressed in the previous *Response and Amendment*, the present invention is based on *specific* procedures performed on patients, not a "roll-up" of procedures under prior art "coding" methods, wherein coding assigns many types of patients groups into the same procedure codes. With the present invention, savings are at the

specific and particular procedure levels, not groups of procedures under a common heading. For additional support, please see at least page 10, line 24 through page 12, line 3; and Fig. 3.

Element (b) is a newly introduced limitation of the computer-implemented method comprising the step of "identifying from the collected data reduction opportunities for reducing waste and costs during the specific clinical procedure". Support for this element can be found in the *Specification* on at least page 11, lines 6-10 (e.g., "...potential waste and cost reduction opportunities are identified"); and page 15, line 1 through page 30, line 18.

Element (c) is clarified to include the limitation of "based upon the identified reduction opportunities", such that the established benchmark is based upon the identified reduction opportunities and at least a portion of the data. Support for establishing a benchmark that is based upon "the identified reduction opportunities" can be found in the *Specification* on at least page 11, lines 10-12 (e.g., "Based upon the identified waste and cost reduction opportunities, a benchmark is established...").

Element (d) was amended in the previous *Response and Amendment* to include the term "specific" and was not objected to by the Examiner for introducing new subject matter. For the same reasons provided above, the term "specific" as related to a clinical procedure is adequately supported in the *Specification* (please see at least page 10, line 24 through page 12, line 3; and Fig. 3).

As all of the elements and limitations presented in clarified Claim 24 are believed to be shown to be adequately supported by the *Specification* as filed on 13 December 2000, Applicant respectfully submits that Claim 24 does not include any new subject matter.

ii. Claim 25

As clarified, Claim 25 provides for a computer-implemented method of increasing resource utilization efficiency and identifying areas to enhance quality, the method comprising the elements of (a) allocating a resource for a specific clinical procedure; (b) conducting the specific clinical procedure during which time at least a portion of the resource is utilized; (c) collecting data related to the allocation of the resource and the conducted specific clinical procedure, wherein the collected data is electronically stored in a database; (d) identifying from the stored data reduction opportunities for reducing waste and costs of the resource for the specific clinical procedure; (e) establishing a benchmark related to the identified reduction opportunities and the utilization of the resource, the benchmark correlating to an average

utilization of the resource for the specific clinical procedure; (f) standardizing the specific clinical procedure based upon the benchmark; and (g) providing the standardization for the specific clinical procedure prior to conducting a subsequent specific clinical procedure, such that fewer resources are allocated.

Element (a) is clarified to include the limitation of "allocating a resource for a specific clinical procedure". Support for allocating resources prior to conducting a clinical procedure can be found in the *Specification* on at least page 10, lines 26-30 (e.g., "The method 300 is implemented by allocating 310 the resources..."); and Fig. 3, Item 310. Also, element (a) was amended in the previous *Response and Amendment* to include the term "specific" and was not objected to by the Examiner for introducing new subject matter. For the same reasons provided above, the term "specific" as related to a clinical procedure is adequately supported in the *Specification* (please see at least page 10, line 24 through page 12, line 3; and Fig. 3).

Element (b) is clarified to include the limitation of "conducting the specific clinical procedure during which time at least a portion of the resource is utilized". Support for element (b) can be found in the *Specification* on at least page 10, lines 26-30 (e.g., "The method 300 is implemented by ... conducting 320 a medical procedure."); Fig. 3, Item 320; and page 17, line 1 through page 30, line 18 (illustrating examples of medical procedures where not all of the allocated resources were utilized). For the same reasons provided above, the term "specific" as related to a clinical procedure is adequately supported in the *Specification* (please see at least page 10, line 24 through page 12, line 3; and Fig. 3).

Element (c) is clarified to include the limitation of "collecting data related to the allocation of the resource and the conducted specific clinical procedure, wherein the collected data is electronically stored in a database". Support for element (c) can be found in the *Specification* on at least page 10, line 30 through page 11, line 5 (e.g., "...the data from allocating the resources and conducting the procedure is collected and stored in the database."); and Fig. 3, Item 330. For the same reasons provided above, the term "specific" as related to a clinical procedure is adequately supported in the *Specification* (please see at least page 10, line 24 through page 12, line 3; and Fig. 3).

Element (d) is clarified to include the limitation of "identifying from the stored data reduction opportunities for reducing waste and costs of the resource for the specific clinical procedure". Support for this element can be found in the *Specification* on at least page 11, lines

6-10 (e.g., "...potential waste and cost reduction opportunities are identified"); page 15, line 1 through page 30, line 18; and Fig. 3, Item 340. For the same reasons provided above, the term "specific" as related to a clinical procedure is adequately supported in the *Specification* (please see at least page 10, line 24 through page 12, line 3; and Fig. 3).

Element (e) is clarified to include the limitation of "establishing a benchmark related to the identified reduction opportunities and the utilization of the resource, the benchmark correlating to an average utilization of the resource for the specific clinical procedure". Support for element (e) can be found in the *Specification* on at least page 11, line 10-14 (e.g., "Based upon the identified waste and cost reduction opportunities, a benchmark is established 350 as to the average utilization of resources for a particular type of procedure."); and Fig. 3, Item 350. For the same reasons provided above, the term "specific" as related to a clinical procedure is adequately supported in the *Specification* (please see at least page 10, line 24 through page 12, line 3; and Fig. 3).

Element (f) is clarified to include the limitation "standardizing the specific clinical procedure based upon the benchmark". Support for element (f) can be found in the *Specification* on at least page 11, lines 15-18 (e.g., "Once a benchmark is established, particular types of procedures may be standardized..."); page 12, lines 1-3 (e.g., "The procedures are standardized by eliminating unnecessary resources as determined by the benchmarks."); Fig. 3, Item 360 and 370; and Claim 1 (as originally filed). For the same reasons provided above, the term "specific" as related to a clinical procedure is adequately supported in the *Specification* (please see at least page 10, line 24 through page 12, line 3; and Fig. 3).

Element (g) is clarified to include the limitation "providing the standardization for the specific clinical procedure prior to conducting a subsequent specific clinical procedure, such that fewer resources are allocated". Support for element (g) can be found in the *Specification* on at least page 13, lines 4-14 (e.g., "The desired [standardized] medical procedure is identified 415 and the resources for the standardized procedure are allocated...the resources allocated 420 ... is at least a portion of the resources requisitioned"); and Fig. 4, Item 410-420. For the same reasons provided above, the term "specific" as related to a clinical procedure is adequately supported in the *Specification* (please see at least page 10, line 24 through page 12, line 3; and Fig. 3).

As all of the elements and limitations presented in clarified Claim 25 are believed to be shown to be adequately supported by the *Specification* as filed on 13 December 2000, Applicant respectfully submits that Claim 25 does not include any new subject matter.

iii. Claim 26

Claim 26 is a previously presented claim that was objected to for new matter, because it depended from Claim 25. For the same reasons stated above (indicating that newly clarified Claim 25 does not introduce new matter), Applicant respectfully submits that Claim 26 does not include any new subject matter. Further, the element of Claim 26 is supported in the *Specification* by at least Claim 2 as originally filed.

iv. Claim 27

Claim 27 is a new claim that depends from original Claim 11. Claim 27 is directed towards the report of Claim 11, adding the additional limitation that the "report comprises a report overlay presenting the established benchmark." Support for the element of Claim 27 can be found in the *Specification* on at least page 7, lines 13-14 (e.g., "These benchmarks are presented as report overlays on pre-formatted reports...").

As the recitation presented in Claim 27 is believed to be shown to be adequately supported by the *Specification* as filed on 13 December 2000, Applicant respectfully submits that Claim 27 does not include any new subject matter.

4. The Claimed Invention is Patentable Subject Matter

Claims 2-20 and 24-26 are rejected under 35 U.S.C. § 101 as not being directed towards patentable subject matter as defined by statute. More specifically, the Examiner bases this rejection on a two-prong test of: (1) whether the invention is within the technological arts; and (2) whether the invention produces a useful, concrete, and tangible results. As noted by the Examiner, the second prong of this test has been met as the recited process produces useful, concrete, and tangible results (*Page 6, lines 3-5 of Office Action*).

The Examiner, however, asserts that Claims 24-26 do not meet the first prong of the test, because the process recites only abstract ideas and does not apply, involve, use, or advance the technological arts since all of the recited steps can be performed in the mind of the user or by the use of a pencil and paper. Applicant clarifies independent Claims 24 and 25 to include a limitation, such that the collected data relating to a specific clinical procedure is ***electronically***

stored in a database. This recitation is fully supported by the originally-filed *Specification*, and one skilled in the art will recognize that a database is well within the technological arts.

As supported by the *Specification* on at least page 6, lines 6-17, a database is a collection of structured data organized in a disciplined fashion to provide quick access and can reside on a server or be distributed on several computers (workstations) via a network. Further, as the collected data is *electronically* stored in the database, the process as claimed cannot be performed in the mind of the user or by the use of a pencil and paper. Accordingly, the claimed process, therefore, applies, involves, uses, and/or advances the technological arts.

As Claims 2-19 and 26-27 depend from presently clarified Claims 24 and 25, Applicant respectfully submits that all pending Claims meet both the first and second prongs of the above-mentioned test and, therefore, are directed towards patentable subject matter as defined by statute.

5. The Present Invention

Conventional clinical operational information management systems utilize previously-stored benchmarks to first check efficiencies, and ***then*** provide cost savings analyses. As patentably distinct from the prior art, the present system identifies reduction opportunities ***before*** the establishment of benchmarks. The present invention uses the data related to the previously identified reduction opportunities to establish the benchmarks. Thus, the present invention as currently recited in the Claims is novel and non-obvious over the known systems.

The present invention is a clinical operational information management system that measures clinical utilization and costs. As illustrated in Fig. 3, the process begins by allocating resources for a specific clinical procedure. The specific clinical procedure is conducted during which time the practitioner utilizes a portion of the allocated resources. During the specific clinical procedure data is collected related to the allocation of the resources and the conducted specific clinical resource. This collected data is electronically stored in a database. From the collected data, the process identifies reduction operations (such as reduction in waste and costs) of the resources for the specific clinical procedure. The identification of reduction operations occurs ***prior to*** establishing a benchmark, because the established benchmark is ***based upon*** the identified reduction operations and the utilization of the resource. After the benchmark has been established, the specific clinical procedure is standardized based upon the benchmark. Subsequently, the standardization can be used for conducting the specific clinical procedure,

such that fewer resources are allocated and used. *See Specification, Page 10, Line 24 - Page 12, Line 11.* Reducing the products and resources required for a procedure, reduces cost and that reduction in cost can be shared with the hospital and the procedure physicians saving the money by following the standardization.

Once the benchmarks are established and procedures are standardized, supplies may be requisitioned automatically from vendors, the supply room, or upon the scheduling of a clinical procedure. Physicians are given information specific information on how their product usage differs from the best practice identified. Also, the costs associated with the utilization of supplies are monitored to determine if cost of supplies and use of supplies are within benchmark parameters. *See Specification, Page 12, Lines 3-11.*

The present invention sets benchmarks not in the abstract, but with specificity, for example, to determine supplies needed to complete a specific procedure, the number of hours to complete a specific procedure, and the number of staff required for a specific procedure to be performed. Each benchmark is related to a specific clinical procedure and, more particularly, to the particular reduction opportunities identified from observing the specific clinical procedure. Accordingly, the established benchmarks are related to the actual care of the same type of patient, with the same type of procedure, benchmarked at a detailed cost and quality level. *See Specification, Page 17, Lines 5-20.*

6. Claim Rejections under 35 U.S.C. § 103

Claims 3-7, 9-18, 20, and 24-25 are rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent Number 5,778,345 to McCartney in view of U.S. Patent Number 5,835,897 to Dang. Claims 2 and 26 are rejected under 35 U.S.C. § 103 as being unpatentable over McCartney in view of Dang and further in view of the article entitled, "Cost Control Incented Many Ways Despite OIG Ruling on Gainsharing," April 12, 2000, Physician Compensation Report (hereinafter CostControl). Claims 8 and 19 are rejected under 35 U.S.C. § 103 as being unpatentable over McCartney in view of Dang and further in view of U.S. Patent Number 6,117,073 to Jones et al.

a. The Pending Claims

Claims 24 and 25 are amended, Claim 20 is canceled, and new dependent Claim 27 is presented. Independent Claims 24 and 25 specifically recite a computer-implemented method that relates to a specific clinical procedure, wherein reduction opportunities are identified prior to

the establishment of a benchmark to be used in standardizing the specific clinical procedure. More particularly, the established benchmark is based upon the identified reduction opportunities.

New dependent Claim 27 is directed towards the generated reports, such that the reports include a report overlay presenting the established benchmark. Such reports provide an easily demonstrated competitive advantage when negotiating with managed care organizations or marketing services to purchasers of care. *See Specification, Page 7, Lines 13-16.*

As amended, Claims 2-19 and 24-27 are currently pending.

b. Claimed Invention Patentably Distinct and Nonobvious

Applicant submits that the pending Claims are patentably distinct and are nonobvious over McCartney, Dang, CostControl, Jones et al., or any combination thereof. For example, none of the cited references disclose a process that includes identifying reduction opportunities for reducing waste and costs for a specific clinical procedure *prior to* establishing a benchmark to be used for standardizing the procedure, such that the established benchmark is *based upon* the identified reduction opportunities.

Indeed, in the present *Office Action*, the Examiner highlights that McCartney discloses a determination of "potential cost savings" (which has been asserted to read on reduction opportunities for the resource for the specific clinical procedure) that compares physician/patient ratios against a benchmark value to confirm whether or not the health care providers are operating efficiently. Moreover, McCartney uses the benchmark comparison to calculate the "potential cost savings" resulting from achieving the benchmarks. *See McCartney, Column 18, Lines 18-37.* If "potential cost savings" reads on (or is equivalent) to the "identification of reduction opportunities" of the present invention, then, as disclosed by McCartney, the identification of these reduction opportunities is occurring *after* the benchmark has already been established. McCartney teaches away from the present invention. That is, in the present invention, however, the "identification of reduction opportunities" occurs *prior to* the establishment of the benchmark, because the establishment of the benchmark is *based upon* the previously identified reduction opportunities.

Unlike the cited the references that use the benchmarks to identify potential cost savings, the present invention uses the collected data (from the allocated resources and the conducted clinical procedure) to identify reduction opportunities to be used to establish a more desirable

and more effective benchmark. Accordingly, a more effective standardization of the clinical procedure can be accomplished. The present invention, therefore, provides benchmarks and standardizations that are more *specific* to the actual clinical procedures that are being conducted at the medical facility. As none of the cited references disclose identifying the reduction opportunities prior to establishing a benchmark to be used subsequently to calculate costs savings, the present invention as claimed is patentably distinct and nonobvious over the cited references.

Independent Claims 24 and 25 include these distinguishable features and all other pending Claims ultimately depend upon Claims 24 and 25. Accordingly, Applicant respectfully submits that Claims 2-19 and 24-27 overcome the rejection of obviousness for the reasons above.

7. Fees

This *Response and Amendment with RCE* is accompanied with the appropriate RCE filing fee of $790.00.

This *Response and Amendment with RCE* is being filed concurrently with a *Petition for Revival of an Application for Patent Abandoned Unintentionally Under 37 C.F.R. § 1.137(b)* with the appropriate petition fee of $1,500.00.

Applicant believes no extension of time fee is due with this *Response and Amendment with RCE*, because of the concurrently filed *Petition for Revival of an Application for Patent Abandoned Unintentionally Under 37 C.F.R. § 1.137(b).* MPEP § 711.03(c) provides that, "A petition for an extension of time under 37 C.F.R. 1.136 and a fee for such an extension of time are not required to be included with the reply."

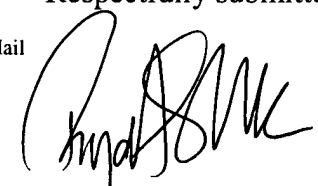
This *Response and Amendment with RCE* provides the application with less than or equal to the total Claims, and independent Claims, provided upon filing, and thus no claim fees are believed due.

A check is enclosed for the above amount. Should any further fees be due, authorization to charge deposit account No. 20-1507 is hereby expressly given.

CONCLUSION

Applicant respectfully request the *Petition for Revival* be granted. Upon such revival, it is believed the present *Response and Amendment with RCE* places the Application in full condition for allowance. Accordingly, Applicant respectfully requests early and favorable action. Should the Examiner have any further questions or reservations, the Examiner is invited to telephone the undersigned Attorney at 404.885.2773.

Respectfully submitted,



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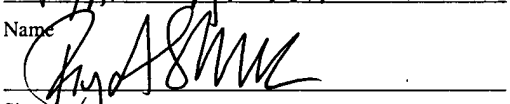
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